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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEI ROGER AOKI, MICHAEL W. GRAYSTON,
STEVEN R. CARLSON and JUDITH M. LEON

Appeal No. 2009-010021
Application No. 10/726,904
Technology Center 1600

Oral Hearing Held: May 4, 2010

Before ERIC GRIMES, TONI SCHEINER, and
DONALD ADAMS, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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MR. DONOVAN: Let me bring out a separate set of papers with regard to this appeal.

In that one, many of the arguments I've made are equally applicable. In that case, again, we do have a Section 112(1) limited to how-to-use enablement rejection. Again because all these cases I viewed them together and they were prosecuted with the same Examiner and the same Examiner agreed we have written description. The first Declaration we got over how to make enablement.

Here, the claimed invention is method for treating strabismus using the neurotoxic component of a botulinum toxin which has a molecular weight of about 150,000. Strabismus is an eye muscle disorder that causes those afflicted to have double vision due to this muscle spasm. And botulinum toxin was used for some years before our filing date as stated in our background, the complex to treat strabismus.

And here the invention was the realization that the neurotoxic component could be used to treat strabismus irrespective of the teachings in the art, i.e. Schantz.

So it is true here we do have two 103 rejections. But as the Examiner has conceded because in one case three of the five references in the combination, and the other rejection, four of the five references are post-art after the 1993 application, if Applicant is granted priority under section 112(1) to the 1993 parent application, then both the 103 rejections become moot because they are based -- most of their references are post-'93 art.

So those rejections will fall if, you know, we decided that we do have, you know, enablement under the 1993 specification.

So I'd like to again direct my arguments to our belief that not only is not undue experimentation but nor is routine experimentation, but no experimentation is required to practice the claimed invention, a method for treating strabismus with the neurotoxic component of a botulinum toxin.

JUDGE GRIMES: Well, rather than go over the ground that we covered just a few minutes ago in the other case, why don't we just incorporate that argument by reference. And for the record, the other case was 2009-011057, Serial Number 10/933,723. And if you could just focus on any facts that are distinctive in this case as compared to the other one.

MR. DONOVAN: Yes. Well, again, of course, the case law I've cited is equally relevant because it is the same type of rejection. I think perhaps to maybe a bit further explain, you know, what the Examiner's rejection is, if I could put myself in his shoes, because again in the Examiner's Answer here, again he says in at least two places in bold font that the priority 1993 application is missing necessary and critical disclosure.

In other words, the Examiner is saying that the 1993 application is missing basic enabling disclosure, or if I may paraphrase him, he is saying that the point of novelty of our invention, this new formulation of the neurotoxic component to get it to work is missing. And it is because we don't disclose formulating the neurotoxic component any way differently from which you would formulate the botulinum toxin complex. The Examiner says, well, in light of Schantz, you don't have this necessary and critical disclosure.

But that is the Examiner's error because it was the invention to realize that you

don't have to formulate the neurotoxic component differently. You could formulate it exactly the same way as the neurotoxic component and obtain a therapeutic effect.

So when the Examiner bases his rejection on a single-art reference and says we are missing necessary and critical disclosure, it is wrong. Because as is set forth by our Declarants, there is no different formulation needed. You can use the formulation in our specification as in the Goodenow Ph.D. thesis, which was published a mere two months after our filing date, but it was a Ph.D. thesis, so it is indicative of the understanding of a person of ordinary skill at the time we filed.

Just as in the Lamanna 1988 publication, the Goodnough Ph.D. thesis sets forth that formulations of the neurotoxic component and of the complex are equally effective when prepared the same way. So that is the substance of my argument.

And perhaps just one final point in light of the latitude the Board has when they decide. In spite of all the art, for example, which shows that the neurotoxic component was known and that it was known how to formulate the neurotoxic component and it was known to inject it into mammals, none of this art points to obviousness of our claimed subject matter because the art talks about injecting the neurotoxic component to recreate a disease condition, to cause bradycardia, to cause botulism, as opposed to a therapeutic effect sought by the claims on appeal.

JUDGE SCHEINER: Could you discuss the Examiner's proposed combination of Balkan and Tse, which would be the references remaining if you're granted priority?

MR. DONOVAN: Yes, be happy to. The 103 rejections, they are both based on five references. And if I could find those. Yes, you know, the first 103 reference is based on five references. Only two of those five have a priority date -- a publication date before 1993, Balkan and Tse, T-S-E.

Of course, the rejection was made based on a combination. And that rejection just like the other 103 rejection becomes moot if priority is granted.

The art talks about the primary references the Examiner provides. As I recall, you know, this is a method for treating strabismus. And their use of -- the botulinum toxin complex to treat strabismus, which we disclose in the background of our application.

And then there is a couple of references on, you know, some properties of the neurotoxic component itself. Those are post-art articles. So the combination will fall if priority is granted.

JUDGE GRIMES: But according to the Examiner, Balkan teaches administration of the entire larger botulinum toxin for treatment of strabismus. And Tse teaches that the purified neurotoxin when injected into the hind leg muscle of a rat would produce local paralysis, which I would guess is the same activity that you would assume or you would expect for the intact toxin.

So why wouldn't you expect that the neurotoxin could be used to treat strabismus like the larger toxin?

MR. DONOVAN: Well, Tse, as I recall, he talks about use of 140 kilodalton molecule. And we are claiming use of the neurotoxic component which has a molecular weight of about 150,000. So personally I believe Tse was using a different molecule or some impure form of a molecule.

And furthermore, as we argued first --

JUDGE SCHEINER: Is there any basis for that other than the difference in molecular weight? Is there any other thing you can point to?

MR. DONOVAN: Yes, I can. The Schantz reference, which is our primary teaching-away reference showing that our distinction of our claims over the art is a patentable distinction, the Schantz reference, remember, says that the neurotoxic component is unlikely to be used clinically and is too labile to have medical purposes.

Schantz discusses and cites the Tse reference and yet still makes these discussions and statements that the neurotoxic component is unlikely to have medical or clinical value.

So, you know, our main teaching-away reference reviewed and discarded the value of this 1982 Tse reference.

JUDGE SCHEINER: But that doesn't -- it doesn't allege that the two -- that what Tse isolated was different, does it?

MR. DONOVAN: Well, let's assume for the moment that it was a similar molecule. I believe we also had a statement in the record that, you know, injecting into rat legs, it is well known to a person of ordinary skill that a response of a rat muscle, in this case the rat leg muscle, firstly is not indicative of the result you will get in a human muscle and not specifically of the small muscles around the eye to treat strabismus.

So it is well known among experimental clinicians that you have to regard with a lot of caution and often you discard results of rat, you know, lower-mammal experimental results.

So I think that is probably the main reason or a reason Schantz disregarded it. Because what may happen in a small rat muscle with an unknown compound

with a different molecular weight from the one we're claiming is not indicative of if you can use it to therapeutically, as shown by the Balkan reference, around the eye.

And I believe we do cite a Moyer reference. Moyer does state that result in a rat muscle with a lot of caution cannot be viewed as indicative of what would happen in a human muscle.

So -- and the other 103 rejection is similar. Again, Balkan is a primary reference and four out of five of the references in the other 103 are post-art. That is, they're published after December 1993.

JUDGE GRIMES: So with respect to that rejection, if we agree with you on the priority issue, then we're left with just Balkan and nothing that teaches the purified neurotoxic component?

MR. DONOVAN: Yes, that is correct. In the second rejection, I mean, Han is a 2001 publication; Kohl, 2000; Aoki, 1999; and the other Aoki has the same December 28, 1993, filing date. So it is not prior art.

So the only prior art in the second rejection is Balkan. So you would be limited in the second rejection to an art item that talks about use of the botulinum toxin complex to treat strabismus. And remember with regard to obviousness, Schantz makes several statements that the neurotoxic component is not going to have clinical use. So it is a useful reference with regard to obviousness.

Of course, with regard to enablement, one considers all the art in light of the guidance in the specification.

JUDGE GRIMES: All right. I think we understand your position. Thank you for coming in.

MR. DONOVAN: Thank you.

Whereupon, the proceedings at 1:47 p.m. were concluded.